Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of efficacy of intra articular injection of mannitol versus hypertonic dextrose prolotherapy on decreasing pain and improvement of functions in patients with knee osteoarthritis

Protocol summary

Study aim
Evaluation of efficacy of intra articular injection of mannitol versus hypertonic dextrose prolothrapy on decreasing pain and improvement of function in patients with knee osteoarthritis randomize clinical trial

Design
This research is a randomized double-blind, controlled clinical trial

Settings and conduct
The patient select from emam reza clinic and rajaee hospital who has knee osteoarthritis.then patient divided into two groups and after obtaining written consent the study begins. in control group hypertonic dextrose is injected and in intervention group monitol is injected then we measure its effect on reducing pain and improving patient function

Participants/Inclusion and exclusion criteria
Inclusion criteria: aged 38 to75 years; both genders; knee radiography anterior standing view have been for the last one month; have symptoms of osteoarthritis include pain, crepitation, and knee joint dryness for at least a month without any extra-articular involvement; any injection of the knee joint during the last three of months. Exclusion criteria: sensitivity reaction to test drug; the patient has done total knee arthroplasty; the patient have diseases mimicking the symptoms of knee pain such as neuropathy and radiculopathy; diseases such as rheumatoid arthritis, Reiter's syndrome, gout; uncontrolled diabetes, HBA1c more than7.5, BMI more than 40; history of knee trauma, fracture patient's mental disorder.

Intervention groups
Intervention group:group that receive knee intra articular injection of mannitol control group: group that receive knee intra articular injection of hypertonic Dextrose.

Main outcome variables
pain, Activity of daily living

General information

Reason for update
wrong translation

Acronym

IRCT registration information
IRCT registration number: **IRCT20190912044756N1**
Registration date: **2020-08-24, 1399/06/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-13, 1400/11/24**
Update count: **2**

Registration date
2020-08-24, 1399/06/03

Registrant information

Name
Nasrin Barzegar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3648 6787

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-20, 1399/02/31

Expected recruitment end date
2020-12-20, 1399/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of efficacy of intra articular injection of mannitol versus hypertonic dextrose prolotherapy on decreasing pain and improvement of functions in patients with knee osteoarthritis

Public title
Evaluation of efficacy of intra articular injection of mannitol in patient with knee osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age: 38 to70 years old Gender: male or female Knee radiography anterior standing view have been for the last three month Have symptoms of osteoartritis include pain, crepitation for at least a month without any extra articular involvment

Exclusion criteria:
Any injection of the knee joint during the last three of months sensitivity reaction to test drug The patient have done total knee arthroplasty The patient have diseases mimicking the symptoms of knee pain such as neuropathy and radiculopathy Diseases such as rheumatoid arthritis, Reiter's syndrom, gout Uncontrolled diabetes,HBA1c more than7.5, BMI more than 40 History of knee trauma,fracture Patient's mental disorder

Age
From **38 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **2**
If both knee are involve,one kneeis in the intervention group and the other is in the control group

Randomization (investigator's opinion)
Randomized

Randomization description
Complete randomize block design with SSPP software is used for randomization and then sealed non-transparent envelopes are used to hide the random sequence

Blinding (investigator's opinion)
Double blinded

Blinding description
Participant: The participant is explained that if they are interested, they can join our research project. two methods used to reduce patient pain input study are explained to the patient. Benefits and possible complications of both methods are described to the patient and the patient is told to randomly fall into one of the intervention groups. If the patient is accepted to admit the study, by random allocation soft ware, the patient falls in to one of two groups. Clinical car giver: we teach the caregiver how to complete the questionnaier. This person is not aware of receiving patient intervention. Researcher: In this study does not have the ability to blind the reseacher because the researcher performs both intervention himself and is aware of receiving each intervention in the group. The outcome assessor of the complete questionnaires is given to person who is not aware of the interventions performed and he/she is asked to determine the level of performance in each person according to the questionnaires. Date analyzer: questionnaire are finally given to a person to review the information. This person doesn't know any of the steps of the work, how to classify and the intervention performed.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz School of Medicin

Street address
No.11, Ansar Ave., Koohbor Blvd., Zerehi

City
Shiraz

Province
Fars

Postal code
7184747811

Approval date
2019-07-28, 1398/05/06

Ethics committee reference number
IR.SUMS.MED.REC.1398.314

Health conditions studied

1

Description of health condition studied
Osteoarthritis of knee

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
knee pain

Timepoint
Two weeks ,foure weeks, eight weeks
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Function of patient
Timepoint
two weeks, four weeks, eight weeks
Method of measurement
Oxford knee score

Intervention groups

1

Description
Intervention group: the group that receive 5cc mannitol 5%, knee intra articular injection ,in three doses as the first dose and two weeks, four weeks , weeks after first dose and control group that receive 5cc of dextrose 25%,inter articular injection,as sequence of intervention group.
Category
Rehabilitation

2

Description
Control group: group who received knee intra articular injection of hypertonic dextrose
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam reza rehabilitation clinic
Full name of responsible person
Mani Ramzi
Street address
Namazi square
City
Shiraz
Province
Fars
Postal code
714737-71348
Phone
+98 71 3212 7000
Email
motahari@sums.ac.ir
Web page address

2

Recruitment center
Name of recruitment center
Rajaee haspital
Full name of responsible person
Amir Reza Mesbahi
Street address
Chamran Blvd
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Shiraz
Province
Fars
Postal code
7194815711
Phone
+98 71 3636 4001
Fax
Email
Rajaeehospital@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Ghasemi
Street address
Khalili Aveno, front of Maaref school
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3628 1506
Email
Info@sums.ac.i
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Nasrin Barzegar

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All available data can be shared after making people unidentifiable.

When the data will become available and for how long
Start access period one year after publishing the results.

To whom data/document is available
everyone can access to this information.

Under which criteria data/document could be used
if the information in this study helps to improve the science process.

From where data/document is obtainable
dr.nasrin.barzegar1975@gmail.com 00989173092357

What processes are involved for a request to access data/document
After sending the desired message, all authors of the study will be consulted all information will be sent within a maximum of three weeks if permitted.

Comments